UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ACTION ALLIANCE OF SENIOR CITIZENS OF GREATER PHILADELPHIA, a Non-profit Philadelphia corporation, Individually and on behalf of all Others similarly situated, Plaintiff, v. ELAN CORPORATION, PLC and SKYEPHARMA, INC. f/k/a BRIGHTSTONE PHARMA, INC., Defendants.	:	IN RE NAPRELAN ANTITRUST LITIGATION No. 02-cv-2095

JEANINE MICHELLE WEBER, Individually and on behalf of all Others similarly situated, Plaintiff, v. ELAN CORPORATION, PLC and SKYEPHARMA, INC. f/k/a BRIGHTSTONE PHARMA, INC., Defendants.	:

CHARLES D. FREDERICKS, JR., On behalf of himself and all Others Similarly Situated,	:
Plaintiff,	:
v.	:
ELAN CORPORATION, PLC and SKYEPHARMA, INC. f/k/a BRIGHTSTONE PHARMA, INC.,	:
Defendants.	:

PLAINTIFFS' JOINT OPENING MEMORANDUM OF LAW IN SUPPORT OF CLASS CERTIFICATION

I. INTRODUCTION

Plaintiffs jointly submit this Memorandum in support of their Joint Motion for Class Certification pursuant to Fed. R. Civ. P. 23(b)(2) and 23(b)(3), seeking certification of a class and designating Plaintiffs as the class representatives:

> All persons or entities throughout the United States and its territories who purchased and/or paid for Naprelan, not for resale, at any time during the period from January 5, 2001, to the present (the "Class Period").

Plaintiffs also seek certification of a subclass of indirect purchasers who are residents of *Illinois Brick*[1] repealer states.[2] Plaintiffs seek injunctive relief,

[1] *Illinois Brick v. Illinois*, 431 U.S. 720 (1977).

[2] This subclass consists of end-payors who purchased or paid for Naprelan in Arizona, Arkansas, California, District of Columbia, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Vermont, and Wisconsin (the "Indirect Purchaser States") (the "Indirect Purchaser Sub-Class"). This subclass alleges violations of state antitrust and consumer fraud statutes.

damages, and disgorgement of Defendants' unlawfully obtained profits from the sale of Naprelan.

Naprelan® ("Naprelan") is the brand name of the controlled-release naproxen drug manufactured and marketed by defendant Elan Corporation, PLC ("Elan"). Naprelan is an analgesic used to treat rheumatoid arthritis, tendonitis, bursitis, and acute gout, among other things. Sales of Naprelan in the United States amounted to approximately $55 million in 1999 alone.

No generic bioequivalent of Naprelan is currently marketed in the United States.[3] The reason for this is simple. Defendant Elan has unlawfully monopolized and attempted to monopolize the market for controlled-release naproxen by filing several sham patent infringement lawsuits against potential generic competitors, and by conspiring with one of those potential generic competitors, Skyepharma, Inc., f/k/a Brightstone Pharma, Inc., ("Skyepharma") to settle the patent lawsuit with an agreement that Skyepharma will keep its generic controlled-release naproxen off the market in exchange for a share of Elan's monopoly profits.

With the filing of each baseless patent infringement lawsuit, Elan improperly extended statutory restraints on trade, thereby preventing public access to a safe, effective, and low-cost generic controlled-release naproxen product. Elan and Skyepharma (collectively, "Defendants") allocated the controlled-release naproxen market between themselves indefinitely by stipulating that, in exchange for

[3] Andrx, a generic manufacturer, announced plans to begin marketing a 500-mg version of Naprelan in September. Apparently, Andrx obtained a waiver of the first-to-file exclusivity provision from the FDA for the 500-mg tablets. As of this writing, however, it is not available and Defendant Elan has continued to block the 375-mg version from entry, as discussed below.

consideration, Skyepharma would not exercise its right to market a generic controlled-release naproxen, for a period of time prevented all other generic companies from reaching the market. This is costing Plaintiffs and the Class they seek to represent millions of dollars in savings they would realize if a generic version of Naprelan were on the market.

II. FACTUAL BACKGROUND

Under the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq*. (the "Act"), the Food and Drug Administration ("FDA") must approve all new prescription drugs. Premarket approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("NDA") with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs are typically (but not necessarily) covered by patents. These patents provide the patent owner with the exclusive right to sell the drug in the United States during the duration of the patents involved, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

Congress enacted the Hatch-Waxman Act in 1984 to expedite the approval of generic drugs. Consumers benefit from the choice and competition. The Hatch-Waxman Act permits a generic drug manufacturer to file an ANDA, which incorporates by reference the safety and effectiveness data developed and previously submitted by the company that manufactured the original, "pioneer" drug. The Act also provides an economic incentive to the first manufacturer to file an ANDA for a

generic version of a particular branded drug – a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its generic drug free from other generic competition.

On January 5, 1996, the FDA approved Elan's Naprelan, thereby clearing the way for Elan to market its controlled-release naproxen product. On June 10, 1997, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,637,320, entitled "Controlled absorption naproxen formulation for once-daily administration" ("the '320 patent"). The '320 patent purportedly claimed several formulations of controlled-release naproxen, including the formulation marketed by Elan as Naprelan. Elan purportedly owns the '320 patent.

The United States District Court for the Southern District of Florida recently held the '320 patent invalid because Elan offered the controlled – release naproxen product that is the subject of the '320 patent for sale more than one year before it filed the application for the '320 patent, in violation of 35 U.S.C. §102(b). *See Elan Corp., PLC v. Andrx Pharmaceuticals, Inc.,* No. 98-CV-7164, 2002 U.S. Dist. LEXIS 4457 (S.D. Fla. March 14, 2002).

Plaintiffs also allege that the '320 patent is invalid and unenforceable for the following reasons:

(a) The claims of the '320 patent were anticipated as and/or obvious in view of numerous prior references, including but not limited to Elan's 1989 annual report and the patent for diltiazem, another Elan product; and

(b) Elan behaved inequitably in front of the PTO by fraudulently withholding material information from the patent examiner, including but not limited to the fact that the

> controlled-release formulation of naproxen tested in an article by *Kelly et al.* (Eur. J. Clin. Pharmacol. (1989) 36:383) was the same formulation of controlled-release naproxen that is recited in the '320 patent.

Although Elan knew that the '320 patent was invalid and unenforceable, Elan nonetheless submitted it to the FDA for listing with the Naprelan NDA.

As of January 5, 1996, the date on which the FDA approved the Naprelan NDA, Elan began to enjoy a five-year statutory monopoly in the market for controlled-release naproxen because of the FDA's determination that the NDA contained a new, previously unapproved active ingredient. During that five-year period, the Act and applicable regulations barred the FDA from approving any ANDA that referenced the Naprelan NDA.

The five-year period of exclusivity, however, ended on January 5, 2001. In the absence of Defendants' anticompetitive activity, beginning January 5, 2001, the FDA would have been free to end Elan's temporary Naprelan monopoly by approving an ANDA for generic Naprelan. 21 U.S.C. § 355(j)(5)(I)(ii).

Skyepharma submitted an ANDA to the FDA for generic Naprelan. Because Skyepharma was the first applicant to file an ANDA that challenged the patent protecting Naprelan, under applicable federal law, it was entitled to market exclusivity on generic controlled-released naproxen for a 180-day period that would begin to run either (1) when Skyepharma began commercial marketing of its controlled-release naproxen product, or (2) when a court decided that the generic product did not infringe the patent subject to Paragraph IV Certification or that such patent is invalid or unenforceable. 21 U.S.C. § 355(j)(5)(B)(iv).

On September 10, 1998, Elan sued Skyepharma (then known as Brightstone) in the United States District Court for the Eastern District of North Carolina (No. 98-cv-701), for alleged infringement of the '320 patent. When it filed that action, Elan knew that the '320 patent was not validly issued, that it was improperly listed by the FDA, and that Skyepharma's product did not infringe the '320 patent. Elan therefore knew that its suit was baseless. Elan's lawsuit was intended to keep generic controlled-release naproxen off of the market – and it did, as the filing of the litigation extended Elan's monopoly beyond January 5, 2001, the date on which the FDA could otherwise have approved an ANDA for a generic version of Naprelan.

On May 13, 1999, Elan and Skyepharma entered into a secret agreement (the "Agreement") "settling" the patent infringement litigation between them. Elan acknowledges the existence of the Agreement, which is subject to discovery in the Florida patent infringement actions against Andrx. However, Elan has refused to produce the Agreement during the course of litigation with Andrx and refuses to disclose its terms.

Pursuant to the Agreement, Skyepharma, the first generic manufacturer to file an ANDA, has not sought to market its generic Naprelan. Upon information and belief, the terms of the Agreement provide for the payment of valuable consideration to Skyepharma for "admitting" that its generic version infringes the '320 patent, obtaining from Elan a license to market its generic, and finally, refraining from actually bringing its generic to market. Because Skyepharma was the first company to submit an ANDA to the FDA seeking permission to market a

generic version of Naprelan, it is entitled to the 180-day period of market exclusivity.

Skyepharma's failure to bring its product to market, pursuant to its Agreement with Elan, has until very recently, prevented the exclusivity period from running, and has the purpose and effect of blocking other generic versions of Naprelan (including Andrx's product) from reaching the market.

Generic drug Andrx manufacturer also filed ANDAs for generic versions of Naprelan (375-mg and 500-mg versions). Elan promptly sued Andrx twice in the Southern District of Florida for the two ANDAs. (Nos. 98-7164 and 00-7057). When Elan filed these lawsuits, it knew that the '320 patent was not validly issued, that it was improperly listed by the FDA, and that Andrx's products did not infringe the '320 patent. Elan therefore knew that its lawsuits were baseless.

On March 14, 2002, the Southern District of Florida held that the '320 patent was invalid – a victory for Andrx. See *Elan Corp., PLC v. Andrx Pharmaceuticals, Inc.*, No. 98-CV-7164, 2002 U.S. Dist. LEXIS 4457 (S.D. Fla. March 14, 2002). This decision cleared the way for the eventual marketing of Andrx's generic Naprelan. Andrx recently announced it has obtained a waiver from the FDA of the first to file limitation and that it intends to begin marketing 500-mg versions of Naprelan beginning this September. However, the 500-mg version is still not available. Additionally, Andrx has also said that it cannot market the 375-mg version because,

absent a final court order, the 30-month waiting period is in effect until December 2002.[4] Thus, to date, no generic versions of Naprelan are on the market.

III. ARGUMENT

A. The Court Should Certify the Class Pursuant to Rules 23(b)(3) and 23(b)(2).

1. Class Certification is Favored in Antitrust Cases.

The antitrust laws are "as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms." *Community Communications Co., Inc. v. City of Boulder, Colo.*, 445 U.S. 40, 56 n.19 (1982), *quoting United States v. Topco Assoc., Inc.*, 405 U.S. 596, 610 (1972). Private enforcement of the antitrust laws is essential to protecting our free-enterprise system.[5] Indeed, the "Supreme Court has called the private civil action a bulwark of antitrust enforcement, whereby the purposes of the federal antitrust laws are best served by the ever-present threat of these types of lawsuits to deter anyone contemplating business misbehavior." *In re Sugar Indus. Antitrust Litig.*, 73 F.R.D. 322, 357 (E.D.Pa. 1976). "[C]lass actions play a crucial role in promoting the enforcement of the antitrust laws." *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 262, 266 (1972)

As a consequence, "the Court of Appeals for the Third Circuit has adopted a liberal construction of Rule 23." *Bunnion v. Consolidated Rail Corp.*, No. 97 – 4877,

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[4] http://news.morningstar.com/news/BW/M08/D28/1030536062304.html.

[5] *See, e.g. Pillsbury Co. v. Conboy*, 459 U.S. 248, 262-63 (1983); *Reiter v. Sonotone Corp.*, 442 U.S. 330, 344 (1979); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130-31 (1969); *Lawlor v. National Screen Serv. Corp.*, 349 U.S. 322, 329 (1955); *Bruce's Juices, Inc. v. American Can Co.*, 330 U.S. 743, 751-52 (1947).

1998 U.S. Dist. LEXIS 7727, at *9 (E.D.Pa. May 14, 1998), *citing Eisenberg v. Gagnon*, 766 F.2d 770, 785 (3rd Cir. 1985).

2. Class Certification Standards.

When making a class action determination, the sole issue before the court is whether the plaintiff is asserting a claim that, assuming its merit, will satisfy the requirements of Federal Rule of Civil Procedure 23. *In re Fine Paper Antitrust Litig.*, 82 F.R.D. 143, 149 (E.D.Pa. 1979). For this purpose, while the substantive allegations contained in the complaint must be taken as true, *In re Commercial Tissue Antitrust Litig.*, 183 F.R.D. 589, 591 (N.D.Fla. 1998), a preliminary inquiry into the merits is sometimes necessary to determine whether the alleged claims can be resolved properly as a class action. *In re Linerboard Antitrust Litig.*, 203 F.R.D. 197, 215 (E.D. Pa. 2001), *aff'd* 2002 U.S. App. LEXIS 18296 (3rd Cir. Sept. 5, 2002).

Federal courts have long recognized the suitability of class actions for pharmaceutical antitrust cases brought against drug manufacturers. *See, e.g., In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 352 (E.D.Mich. 2001); *In re Synthroid Marketing Lit.*, 188 F.R.D. 295 (N.D.Ill. 1999) (certifying class of consumers who purchased Synthroid); *In re Synthroid Marketing Litig.*, 188 F.R.D. 287 (N.D.Ill. 1999) (certifying class of health insurers).[6]

To certify a class under Rule 23(a), plaintiff must satisfy each requirement in Rule 23(a), as well as at least one of the separate provisions of Rule 23(b). *In re*

[6] *See also In re Antibiotics Antitrust Actions*, 333 F. Supp. 278 (S.D.N.Y. 1971); *Sol S. Turnoff Drug Distrib. Inc. v. N.V. Nederlandsche Combinatie Voor Chemische Industrie*, 51 F.R.D. 227 (E.D.Pa. 1970) (certifying class of purchasers of quinine products for wholesale and retail distribution in the United States); *West Virginia v. Chas. Pfizer & Co., Inc.*, 314 F. Supp. 710 (S.D.N.Y. 1969). (same for antibiotics).

Plastic Cutlery Antitrust Litig., 1998 WL 135703 at *2 (E.D. Pa.1998); *In re Flat Glass Antitrust Litig*., 191 F.R.D. 472, 476-77 (W.D.Pa. 1999). As shown below, this action meets all of the requirements of Rule 23(a) as well as the requirements of Rules 23(b)(2) and 23(b)(3).

3. This Action Satisfies the Requirements of Rules 23(a) and 23(b)(3).

Rule 23(a) provides that in order to proceed as a class action:

> One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). In addition to meeting the criteria of Rule 23(a), a class must also meet the requirements of one of Rule 23(b)'s subsections. Rule 23(b)(3) provides that a class action may be maintained if "[t]he questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and . . . a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed.R.Civ.P. 23(b)(3).

a. Numerosity is Clearly Present.

The first requirement in maintaining a class action under Rule 23(a) is that the proposed class be so numerous that joinder of all members is "impracticable." Fed. R. Civ. P. 23(a)(1). This requirement requires only a showing that joining all class members would be difficult or inconvenient. *In re Fine Paper Antitrust Litig*., 82 F.R.D. 143, 149 (E.D.Pa. 1979). "The exact number or identity of the members of

the plaintiff class is not required." *Hanrahan v. Britt*, 174 F.R.D. 356, 362 (E.D.Pa. 1997); *Cumberland Farms, Inc v. Browing-Farris, Ind.* 120 F.R.D. 642, 645 (E.D.Pa. 1988). "Classes in excess of one hundred members are typically found to satisfy the numerosity requirement." *Rendler v. Gambone Bros. Dev. Co.*, 182 F.R.D. 152, 157 (E.D. Pa. 1998). Plaintiffs herein have alleged that more than a million Americans have purchased Naprelan. Thus, members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. *See, e.g., In re Linerboard Antitrust Litig.*, 203 F.R.D. 197, 205 (E.D.Pa. 2001), *aff'd* 2002 U.S. App. LEXIS 18296 (3d Cir. Sept. 5, 2002).

b. Common Questions of Law or Fact Exist and Predominate.[7]

Commonality under Rule 23(a)(2) focuses on whether there exist questions of law or fact common to the class.[8] If these common questions predominate over individual questions, then Rule 23(b)(3)'s predominance requirement is met. *See In re Prudential Ins. Co. of America Sales Practice Litig.*, 148 F.3d 283, 309 (3d Cir. 1998). *Cardizem*, 200 F.R.D. at 335. The Third Circuit has a "low threshold for

[7] This section addresses both the existence of common questions of law or fact under 23(a)(2) and their predominance over individual questions under 23(b)(3).

[8] The commonality and typicality requirements of Rule 23(a) overlap to a great degree and courts often discuss these concepts together. *See, e.g., In re Prudential Ins. Co. of America Sales Practices Litig.*, 148 F.3d 283, 311 (3rd Cir. 1998); *Hassine v. Jeffes*, 846 F.2d 169, 176-77, at n.4 (3d Cir. 1988); *Williams v. Empire Funding Corp.*, 183 F.R.D. 428, 438 (E.D.Pa. 1998) (noting that "[b]oth commonality and typicality serve as guideposts for determining whether...maintenance of a class action is economical and whether the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence") (citation omitted). However, there are differences: "commonality"...evaluates the sufficiency of the class itself, [while] 'typicality'...evaluates the sufficiency of the named plaintiff." *Hassine*, 846 F.2d at 176-77, n.4. *See also Bunnion*, No. 97 – 4877, 1998 U.S. Dist. LEXIS 7727, at *11 – 12. In the interest of completeness, Plaintiffs discuss commonality and typicality separately to demonstrate that each requirement is satisfied here.

commonality." *In re Flat Glass Antitrust Litig.*, 191 F.R.D. 472, 478 (W.D. Pa. 1999). Because the [commonality] requirement may be satisfied by a single common issue, it is easily met. *See Linerboard*, 203 F.R.D. at 205. Moreover, "[a] finding of commonality does not require that all class members share identical claims, and indeed factual differences among the claims of the putative class members do not defeat certification." *Prudential*, 148 F.3d at 310 (internal quotation marks omitted).

Rule 23(b)(3)'s predominance requirement is also met because these common questions of law and fact predominate:

- Whether Defendants engaged in a combination or conspiracy to allocate the market for Naprelan;
- The duration and extent of the alleged combination or conspiracy;
- Whether the alleged combination or conspiracy violates Section 1 of the Sherman Antitrust Act[9];
- The effect of the alleged combination or conspiracy upon the price of Naprelan;
- Whether Elan has monopolized or attempted to monopolize the market for Naprelan;
- How to properly define the relevant geographic and product markets;
- Whether Defendants' conduct is subject to per se treatment under the antitrust law; and if not whether any procompetitive justifications exist for the allegedly illegally restraint of trade;

[9] The common questions as to whether Defendants violated the Sherman Act are the same for the state antitrust claims. Each of the indirect purchaser state antitrust statutes prohibiting illegal monopolies and attempts to monopolize have the same essential elements as federal claims for violations of Sections 1 and 2 of the Sherman Act. In fact, in interpreting equivalent state antitrust statutes, courts either follow federal Sherman Act precedent, find federal case law persuasive, or both. *See, e.g., In re Cardizem CD Antitrust Litig.*, 105 F. Supp.2d 682, 692-693 and at n.6 (collecting cases).

- The measure of damages in the Indirect Purchaser States, and the extent of Defendants' unjust enrichment; and

- Whether Plaintiffs are entitled to injunctive relief under the Clayton Act.

c. The Claims of the Representative Plaintiffs are Typical of the Claims of the Class.

Rule 23(a)(3) requires that the representative plaintiffs' claims be "typical" of the claims of the class. The typicality requirement "is a safeguard against interclass conflicts, ensuring that the named plaintiff's interests are more or less coextensive with those of the class." *Cumberland Farms*, 120 F.R.D. at 646 (citation omitted). The representative plaintiffs' claims are "typical" where, as here, they arise from the same course of conduct giving rise to the claims of the other class members, and where the claims are based on the same legal theory. *See Flat Glass*, 191 F.R.D. at 479.

"The threshold for establishing typicality is low." *Seidman v. American Mobile Systems*, 157 F.R.D. 354, 360 (E.D.Pa. 1994). Thus, typicality "does not require that the [representative plaintiffs'] circumstances be the same, only that the harm complained of be common to the class." *Gaskin v. Pennsylvania,* No. 94 – 4048, 1995 U.S. Dist. LEXIS 8136, at *10 (E.D.Pa. June 12, 1995). In fact, even relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories or where the claim arises from the same practice or course of conduct. *Linerboard*, 203 F.R.D. at 207.[10]

[10] In *Prudential*, the Third Circuit observed that "cases challenging the same unlawful conduct which affects both the named plaintiffs and the putative class usually satisfy the typicality requirement

In this case, Plaintiffs' claims arise from the same conduct as the claims of the respective Class members, and the relief Plaintiffs seek is common to the Class. See *Cardizem*, 200 F.R.D. at 335; *In re Playmobil Antitrust Litig.*, 35 F. Supp. 2d 231, 241-42 (E.D.N.Y. 1998). As a result of Defendants' unlawful monopolization and attempted monopolization of the market for Naprelan through the filing of baseless litigation and providing misinformation to the FDA and the PTO, Plaintiffs and the Class members paid supra-competitive prices. These allegations, which must be accepted as true for purposed of class certification, demonstrate that Plaintiffs' claims are typical of the claims of all Class members in satisfaction of Rule 23 (a)(3).[11]

Each of the individual and third-party payor Class members have performed one uniform function which is the crux of the litigation – they have all paid supra-competitive retail prices for Naprelan. In some instances, either the consumer or the third party payor has paid the entire amount of the prescription; at other times the consumer has paid a portion and the third-party payor has co-paid a portion. As individuals and entities that have all paid for these drugs, the Class representatives and the members of the Class all share one critical and material fact in common: they all overpaid for Naprelan as a result of Defendants' anticompetitive behavior.

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irrespective of the varying fact patterns underlying the individual claims." 148 F.3d at 311, *quoting Neal v. Casey*, 43 F. 3d 48 (3d. Cir. 1994).

[11] *See, e.g.*, *In re Potash Antitrust Litig.*, 159 F.R.D. 682, 690 (D.Minn. 1995)("a strong similarity of legal theories will satisfy the typicality requirement despite substantial factual differences"); *In re Aluminum Phosphide Antitrust Litig.*, 160 F.R.D. 609, 613 (D.Kan. 1995) ("typicality element requires that representative plaintiffs possess the same interest and suffer the same injuries as proposed class members"); *In re Catfish Antitrust Litig.*, 826 F. Supp. 1019, 1035 (N.D.Miss. 1993)("a claim by a representative party may be deemed 'typical' if it is one which should be 'reasonably expected' to be raised by members of the proposed class.")

d. The Representative Plaintiffs Will Fairly and Adequately Protect the Interests of the Class.

The final requirement of Rule 23(a) is that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). In the Third Circuit, this prerequisite involves a two-pronged inquiry: (1) whether the representatives and their attorneys will competently, responsibly and vigorously prosecute the suit, and (2) whether plaintiffs' interests are antagonistic to those of the class. *See In re General Motors Corp. Pick-up Truck Fuel Tank Prod. Liab. Litig.*, 55 F. 3d 768, 800-01 (3d Cir. 1995).

As to the first prong, experienced antitrust counsel represent the named Plaintiffs.[12] "[T]here is no ground supposing the plaintiffs will not adequately represent the class." *In re Glassine*, 88 F.R.D. 302, 306 (E.D.Pa. 1980).

As to the second prong, the representative plaintiffs and each member of the proposed Class have a similar interest in seeing liability established against the defendants. By pursuing this litigation, each representative Plaintiff will necessarily advance the common interests of all other Class members. Each of the Class members shares the identical objectives of establishing liability and obtaining damages and restitution. No conflict of interest exists as to either of these goals as all members of the Indirect Purchaser subclass will desire to recover as damages that portion of the overpayment that is attributable to their payments. All Plaintiffs will likewise have a unified interest in disgorging Defendants' ill-gotten

[12] Should the Court desire, Plaintiffs' counsel can submit resumes demonstrating the skill, experience, and expertise of each firm.

gains resulting from the overpayments for Naprelan made by Plaintiffs and the members of the Class.

The claims of the third-party payor Plaintiffs and consumer Plaintiffs are the same. In the era of managed care economics prevailing during the Class Period, consumers and third-party payors typically pay pharmacies the retail price charged by the pharmacy for that prescription, with the consumer usually paying a co-payment and the third-party provider paying the balance. Consumers without third-party payors pay the entire retail price. Consumers and third-party payors both pay less for generics. Both third-party payors and consumers have the same incentives and will use the same proofs to establish liability and damages and to seek to collect their respective shares of the overcharges for Naprelan awarded as damages and disgorged in restitution. The adequacy requirement of Rule 23 (a)(4) thus is fully satisfied.

e. Class Treatment is Superior.

In addition to the predominance of common questions, Rule 23(b)(3) requires that the Court determine that the class action device is superior to other available methods for the fair and efficient adjudication of these controversies.

Considerations of judicial economy and access to justice underscore the superiority of the class action in this case. Class members' individual claims are relatively small when measured against the prohibitive cost of prosecution of this type of complex litigation, and a class action stands as the only practical method by which the vast majority of plaintiffs and members of the Class can litigate their

claims against Defendants. *See, e.g., In re Synthroid*, 188 F.R.D. 295, 302 (N.D.Ill. 1999). Abandonment of the Plaintiffs' and the Class' claims would, of course, run counter to the public policy embodied in the antitrust statutes and presumably leave Defendants in possession of unlawful profits. *See In re Folding Carton Antitrust Litig.*, 75 F.R.D. 727, 733 (N.D.Ill. 1977) (class actions "reinforce the regulatory scheme by providing an additional deterrent beyond that afforded either by public enforcement or by single-party private enforcement").

Plaintiffs are aware of no insurmountable management difficulties that will be encountered in the litigation on behalf of the Class. Difficulties in management of class actions are significant only if they make the class action less fair and efficient than other available techniques. *In re Domestic Air Trans. Antitrust Litig.*, 137 F.R.D. 677, 693 (N.D. Ga. 1991). *See also, Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 1994 U.S. Dist. LEXIS 12652, at *8 (N.D.Cal. Sept. 2, 1994) ("Despite the complexity of determining individual damages, other methods of adjudicating this controversy would appear to be even more complex and less efficient."). While the Class is indeed large, management should not be any more difficult than other complex class litigation. In *Domestic Air*, for example, a class consisting of at least 12.5 million persons and 400 million transactions was certified. 137 F.R.D. at 694. *See also In re Disposable Contact Lens Antitrust Litigation*, 170 F.R.D. 524 (M.D.Fla. 1996) (class of 15 to 18 million replacement contact lens purchasers); *Appleton Electric Co. v. Advance United Expressways*, 494 F.2d 126 (7th Cir. 1974) (several million member plaintiff class and thousand-plus member defendant class);

In re NASDAQ Market-Makers Antitrust Litigation, 169 F.R.D. 493, 528 (S.D.N.Y. 1996) ("the size of the class militates in favor of, not against, class certification").

4. This Action Also Fulfills the Requirements of Rule 23(b)(2).

Rule 23(b)(2) provides for class certification when the defendant has "acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." *Baby Neal v. Casey*, 43 F.3d 48, 58 (2nd Cir 1994). In addition to their claim for damages, Plaintiffs also request an injunction against Defendants' anticompetitive conduct. In addition to certification of the Class pursuant to Rule 23(b)(3), therefore, certification of the Class pursuant to Rule 23(b)(2) is also appropriate. "Courts have certified antitrust class actions both under Rule 23(b)(2) and (b)(3) if the requirements of each rule are satisfied." *See also NASDAQ*, 169 F.R.D. at 515 ("Nothing in the language of Rule 23 precludes certification of both an injunctive class and a damages class in the same action. In fact, where injunctive relief and damages are both important components of the relief requested, court[s] have regularly certified an injunctive class under Rule 23(b)(2) and a damages class under Rule 23(b)(3) in the same action.")

Unlike damages claims of indirect purchasers under the federal antitrust laws, the Third Circuit has held that indirect purchasers of brand-name prescription drugs, such as consumers and third party payors, have standing to seek and injunction under the Clayton Act. *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 402 (3rd Cir. 2000). For the purposes of determining whether the

proposed class should be certified under Rule 23(b)(2), the essential consideration is whether the complaint alleges that plaintiffs have been injured by defendants' conducted based on practices applicable to the entire class. *T.B. v. School Dist. of Philadelphia*, 1997 WL 786448 at *6 (E.D.Pa. 1997). Here, the fact that Plaintiffs and members of the Class are subject to paying supra-competitive prices for Naprelan suffices to support their common claim against Defendants. *See Baby Neal*, 43 F.3d at 63 ("The fact that all plaintiffs are subject to the risk of deprivation of services to which they are currently entitled (or which they may at some point in the future require) suffices to support their common claim against [defendant].").

Furthermore, Plaintiffs and the Class members will benefit from relief designed to assure Defendants' compliance with the applicable standards. Because this action challenges conduct generally applicable to the Class and because the Court can enter appropriate equitable and declaratory relief, this action patently satisfies the 23(b)(2) standard. If Plaintiffs prove their case, they are entitled not only to restitution for the excessive prices they have already paid (which is the subject of the Rule 23(b)(3) class), but also to an injunction preventing Defendants from engaging in the same unlawful techniques to acquire and maintain a future monopoly. *See Davis v. Southern Bell Tel. & Tel. Co.*, 1993 WL 593999 at *7 (S.D.Fla. Dec. 23, 1993). Defendants' continuing unlawful acts of monopolization and attempted monopolization certainly threaten continuing harm to all Class members. *See NASDAQ*, 169 F.R.D. at 516 ("Unless enjoined and made subject to equitable relief, Defendants' alleged conspiracy will continue to inflate spreads for

the benefit of Defendants and to the detriment of the Class."); *In re Warfarin*, 214 F.3d at 402 ("Unless enjoined, DuPont's unlawful conduct will continue unchecked and the class will continue to bear the financial brunt of the antitrust violations.").

In sum, as the injunctive relief sought by Plaintiffs is an important aspect of the case, the Court should certify the Class pursuant to Rule 23(b)(2) as well as Rule 23(b)(3).

IV. CONCLUSION

The primary purpose behind Rule 23 is the vindication of the rights of people who would not have the economic power or incentive to bring a defendant into court to redress a wrong done to them. Thus, the objective is to aggregate small claims to make the cost and effort of litigation economically feasible and to allow courts to redress wrongs that would otherwise be done with impunity. *See Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 616 (1997). The Supreme Court has adhered to the principle reiterated in *Amchem* for over 20 years:

> The aggregation of individual claims in the context of a classwide suit is an evolutionary response to the existence of injuries unremedied by the regulatory action of government. Where it is not economically feasible to obtain relief within the traditional framework of a multiplicity of small individual suits for damages, aggrieved persons may be without any effective redress unless they may employ the class-action device.

Deposit Guaranty Nat'l Bank v. Roper, 445 U.S. 326, 339 (1980).

Here, common questions of law and fact prevail and a class action is unquestionably the only device by which class members can adjudicate their claims.

Dated: _____

Respectfully submitted,

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